| 1 | ROBBINS GELLER RUDMAN & DOWD LLP | | | | |
|----|---|-----------------------------------|--|--|--|
| 2 | DAVID C. WALTON (167268) 655 West Broadway, Suite 1900 San Diego, CA 92101-8498 | | | | |
| 3 | | | | | |
| 4 | Telephone: 619/231-1058 | | | | |
| 5 | 619/231-7423 (fax) dwalton@rgrdlaw.com | | | | |
| 6 | | | | | |
| 7 | Attorneys for Plaintiff | | | | |
| 8 | [Additional counsel appear on signature p | rage.] | | | |
| 9 | | | | | |
| 10 | UNITED STATES DISTRICT COURT | | | | |
| 11 | SOUTHERN DISTRICT OF CALIFORNIA | | | | |
| 12 | GAIL FIALKOV, Individually and on Behalf of All Others Similarly Situated, | Case No. <u>'15CV1458 AJB DHB</u> | | | |
| 13 | Plaintiff, | <u>CLASS ACTION</u> | | | |
| 14 | vs. | COMPLAINT FOR VIOLATION OF | | | |
| 15 |) | THE FEDERAL SECURITIES LAWS | | | |
| 16 | CELLADON CORPORATION, () KRISZTINA M. ZSEBO and () REBECQUE J. LABA, () | | | | |
| 17 | Defendants. | | | | |
| 18 |) | DEMAND FOR JURY TRIAL | | | |
| 19 | | | | | |
| 20 | | | | | |
| 21 | | | | | |
| 22 | | | | | |
| 23 | | | | | |
| 24 | | | | | |
| 25 | | | | | |
| 26 | | | | | |
| 27 | | | | | |
| 28 | | | | | |

Plaintiff, individually and on behalf of all others similarly situated, by her undersigned attorneys, for her complaint against defendants, alleges the following based upon personal knowledge as to plaintiff and plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through plaintiff's attorneys, which included, among other things, a review of Securities and Exchange Commission ("SEC") filings by Celladon Corporation ("Celladon" or the "Company"), as well as media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION AND OVERVIEW

- 1. This is a securities class action on behalf of all persons who purchased or otherwise acquired Celladon publicly traded securities between July 7, 2014 and June 25, 2015, inclusive (the "Class Period"), against Celladon and certain of its officers and/or directors for violations of the Securities Exchange Act of 1934 ("1934 Act"). These claims are asserted against Celladon and certain of its officers and/or directors who made materially false and misleading statements during the Class Period in press releases and filings with the SEC and in oral statements to the media, securities analysts and investors.
- 2. Celladon is a clinical-stage biotechnology company which is focused on the development of cardiovascular gene therapy and calcium dysregulation. The Company's lead product candidate is MYDICAR® ("MYDICAR"), which uses genetic enzyme replacement therapy to correct the Sarco/endoplasmic reticulum Ca2+-ATPase, or "SERCA2a," enzyme deficiency in heart failure patients that results in inadequate pumping of the heart.
- 3. On April 26, 2015, Celladon issued a press release announcing that the Company's Phase 2b CUPID2 trial of MYDICAR did not meet its primary and secondary goals. CUPID2 was a randomized, double-blind, placebo-controlled multinational trial evaluating a single, one-time, intracoronary infusion of MYDICAR

- versus placebo added to a maximal, optimized heart failure drug and device regimen. The Company reported that "the primary endpoint comparison of MYDICAR to placebo resulted in a hazard ratio of 0.93 (0.53, 1.65 95%CI) (p=0.81), defined as heart failure-related hospitalizations or ambulatory treatment for worsening heart failure" and the "secondary endpoint comparison of MYDICAR to placebo, defined as all-cause death, need for a mechanical circulatory support device, or heart transplant, likewise failed to show a significant treatment effect."
- 4. As a result of this news, the price of Celladon stock plummeted \$11.04 per share to close at \$2.64 per share on April 27, 2015, a decline of 80% on volume of 32 million shares.
- 5. On June 1, 2015, Celladon issued a press release announcing the abrupt resignation of defendant Krisztina M. Zsebo ("Zsebo") as Chief Executive Officer ("CEO") and a director.
- 6. Then, on June 26, 2015, before the market opened, Celladon issued a press release announcing the suspension of its plans for further research or development of its MYDICAR program and other pre-clinical programs, and indicating the possibility that the Company could be liquidated with net cash available to shareholders of \$25-\$30 million.
- 7. As a result of this news, the price of Celladon stock dropped \$0.85 per share to close at \$1.35 per share on June 26, 2015, a decline of 38% on volume of 9 million shares.
- 8. As a result of defendants' false statements, Celladon securities traded at artificially inflated prices during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending the Company's stock price down 95% from its Class Period high and causing economic harm and damages to class members.

JURISDICTION AND VENUE

- 9. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the 1934 Act, 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. §240.10b-5.
- 10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the 1934 Act.
- 11. Venue is proper pursuant to §27 of the 1934 Act and 28 U.S.C. §1391(b). Celladon's principal place of business is located at 11988 El Camino Real, Suite 650, San Diego, California. Many of the acts charged herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.
- 12. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the NASDAQ stock market.

THE PARTIES

- 13. Plaintiff Gail Fialkov purchased Celladon publicly traded securities during the Class Period as set forth in the attached certification and was damaged thereby.
- 14. Defendant Celladon is a clinical-stage biotechnology company. It maintains its headquarters at 11988 El Camino Real, Suite 650, San Diego, California. Celladon's common stock is traded under the ticker "CLDN" on the NASDAQ, an efficient market.
- 15. Defendant Zsebo was, at all relevant times, CEO and a director Celladon until her resignation on June 1, 2015. During the Class Period, defendant Zsebo sold 226,397 shares of her Celladon stock for proceeds of over \$4.1 million.

- 16. Defendant Rebecque J. Laba ("Laba") is, and at all relevant times was, Vice President, Finance and Administration, of Celladon. Defendant Laba sold 79,012 shares of her Celladon stock for proceeds of over \$1.3 million.
- 17. The defendants referenced above in ¶¶15-16 are collectively referred to herein as the "Individual Defendants." The Individual Defendants made, or caused to be made, false statements that caused the prices of Celladon securities to be artificially inflated during the Class Period.
- 18. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Celladon's quarterly reports, shareholder letters, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. They were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to and were being concealed from the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein.

FRAUDULENT SCHEME AND COURSE OF BUSINESS

19. Defendants are liable for: (i) making false statements; or (ii) failing to disclose adverse facts known to them about Celladon. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Celladon publicly traded securities was a success, as it: (i) deceived the investing public regarding Celladon's prospects and business; (ii) artificially inflated the prices of Celladon publicly traded securities; (iii) permitted defendants Zsebo and Laba and other insiders Company's insiders to sell 388,661 shares of their Celladon stock at

1

4

5

7

8 9 10

11

12

14

15 16

18 19

20

21

22 23

24

26

27

artificially inflated prices during the Class Period for proceeds of nearly \$7 million; and (iv) caused plaintiff and other members of the Class (as defined below) to purchase Celladon publicly traded securities at artificially inflated prices.

SCIENTER ALLEGATIONS

20. During the Class Period, the defendants had the motive and opportunity to commit the alleged fraud. Defendants also had actual knowledge of the misleading statements they made and/or acted in reckless disregard of the true information known to them at the time. In doing so, the defendants participated in a scheme to defraud and committed acts, practices and participated in a course of business that operated as a fraud or deceit on purchasers of Celladon securities during the Class Period.

BACKGROUND

- 21. Celladon is a clinical-stage biotechnology company. The Company is in the business of calcium dysregulation by targeting SERCA enzymes to develop therapies for diseases with tremendous unmet medical needs. SERCA enzymes are a family of enzymes that play an integral part in the regulation of intra-cellular calcium in all human cells. Celladon's therapeutic portfolio for diseases characterized by SERCA enzyme deficiency includes both gene therapies and small molecule compounds. MYDICAR uses gene therapy to target SERCA2a, which is an enzyme that becomes deficient in patients with heart failure. Its lead product candidate, MYDICAR, uses genetic enzyme replacement therapy to correct the SERCA2a enzyme deficiency in heart failure patients that results in inadequate pumping of the heart. MYDICAR is delivered directly to the heart in a routine outpatient procedure, similar to an angiogram, in a cardiac catheterization laboratory.
- 22. Following the completion of Celladon's CUPID1 trial, it received Fast Track designation from the U.S. Food and Drug Administration ("FDA") in December 2011 for MYDICAR for the treatment of systolic heart failure in New York Heart Association Class III/IV heart failure patients. Subsequently, it held an End-of-Phase 2 meeting with the FDA, as a result of which the FDA indicated that: data supported

1 | pr 2 | sa 3 | w 4 | h 6 5 | d 6 | a 6 7 | ft 8 | a 6 9 | st

proceeding to a Phase 3 clinical trial with high-dose MYDICAR; Celladon's proposed safety database, which would include approximately 610 patients (one-half treated), would be acceptable if the safety profile was similar to CUPID1; time-to-recurrent heart failure-related hospitalizations, in the presence of terminal events (all-cause death, left ventricular assist device ("LVAD") implantation, and heart transplant), was acceptable as the primary endpoint, pending details of the statistical analysis plan and further discussion with agency statisticians; and a single clinical trial would be acceptable for a biologics license application, or BLA, submission, assuming statistically significant primary outcome and strong concordance of primary and secondary endpoint analyses.

- 23. In 2012, Celladon obtained a Special Protocol Assessment, or SPA, whereby the FDA agreed to use time-to-multiple heart failure-related hospitalizations as the primary endpoint for a MYDICAR Phase 3 pivotal trial. The ongoing CUPID2 trial used a similar clinical protocol with identical endpoints as agreed to in the SPA.
- 24. Celladon also held a Type A meeting with the FDA, as a result of which the FDA approved a 572-patient Phase 3 trial protocol under the SPA guidance and agreed that the design and planned analyses of this trial would be sufficient to provide data that, depending on outcome, could support a BLA submission. Pursuant to the SPA, the Company also obtained an agreement from the FDA that the primary efficacy endpoint of time-to-recurrent heart failure-related hospitalizations in the presence of terminal events would be acceptable for a pivotal trial of MYDICAR. This endpoint counts multiple heart failure-related hospitalizations per patient, and "corrects" for the occurrence of terminal events. Referring to the published FDA guidance, Celladon suggested that the FDA may not require it to complete a Phase 3 trial if the results of the CUPID2 trial meet the requirements necessary to support a BLA submission based on a single trial as outlined by the FDA.
- 25. In April 2014, MYDICAR was granted "Breakthrough Therapy" designation by the Center for Biologics Evaluation and Research ("CBER") division

of the FDA. The criteria for breakthrough therapy designation require preliminary clinical evidence indicating that the drug may demonstrate a substantial improvement over existing therapies on at least one clinically significant endpoint. A breakthrough therapy designation conveys all of the fast track program features, as well as a commitment that the FDA will work closely with the drug sponsor on an efficient drug development program. The statute calls for reducing exposure of patients to a potentially less-effective active control drug. The FDA expedites the development and review of a breakthrough therapy by intensively involving senior managers and experienced review staff in a proactive, collaborative, cross-disciplinary review.

and review of a breakthrough therapy by intensively involving senior managers and experienced review staff in a proactive, collaborative, cross-disciplinary review.

26. Based on the CUPID1 results and following discussions with the FDA, Celladon advanced MYDICAR to the CUPID2 Phase 2b trial. The primary objective of the CUPID2 trial was to determine the efficacy of a single intracoronary infusion of high-dose MYDICAR compared to placebo, in conjunction with maximal optimized heart failure therapy, in reducing the frequency of and/or delaying heart failure-related hospitalizations in patients with systolic heart failure (having an ejection fraction less than 35%) who are at increased risk of terminal events based on elevated levels of

27. Ejection fraction, or EF, is the measurement used to describe the contractility of the heart. The dose being used in the CUPID2 trial was equivalent to the high dose used in CUPID1. Patients were randomized in parallel to high-dose MYDICAR or placebo in a 1:1 ratio. Approximately 250 patients were to be enrolled to obtain at least 186 adjudicated heart failure-related hospitalizations. The primary efficacy endpoint was time-to-recurrent heart failure-related hospitalizations in the presence of terminal events at the time of primary analysis data cutoff.

natriuretic peptides or a recent heart failure-related hospitalization.

DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

28. On July 7, 2014, Celladon issued a press release announcing that it was launching two new clinical development initiatives for MYDICAR. The release stated in pertinent part:

"We believe these new development initiatives will further increase the value of Celladon's pipeline and potentially allow us to broaden the clinical utility of MYDICAR for a wide range of patients," said Krisztina Zsebo, Ph.D., Chief Executive Officer of Celladon. "Early data underlying these initiatives have shown promising results and we look forward to understanding MYDICAR's potential in both additional settings."

Celladon plans to initiate a 100 patient Phase 2a trial with MYDICAR in ESRD patients undergoing surgery for AVF creation in preparation for hemodialysis. The trial will evaluate MYDICAR's effect on preventing neointimal hyperplasia and improving blood flow in treated vessels, as a means to enhance the AVF maturation process. AVF maturation failure is a common problem in approximately half of the patients that undergo the procedure. There are currently no U.S. Food and Drug Administration (FDA) approved products to enhance AVF maturation. Initial results from this study are expected in 2015.

The Company also plans to initiate a pilot, 24 patient, Phase 1/2 study of MYDICAR in advanced heart failure patients with systolic dysfunction that have been previously excluded from MYDICAR studies in this indication due to pre-existing levels of neutralizing antibodies against the AAV1 vector, which can block MYDICAR's activity. This study will examine whether plasma exchange can remove AAV1 neutralizing antibodies from the circulation in advance of MYDICAR administration. Based on Celladon's database of blood samples to date, the Company estimates that approximately 60 percent of all patients in the United States currently have AAV1 neutralizing antibodies. The Company expects to initiate this study in 2014, and initial results are expected in 2015.

In addition to these clinical trials, Celladon recently completed enrollment of the 250 patient Phase 2b CUPID2 trial evaluating the efficacy of MYDICAR in reducing the frequency of, or delaying heart failure-related hospitalizations. This randomized, double-blind, placebo-controlled, multinational trial is evaluating a single intracoronary infusion of MYDICAR versus placebo added to a maximal, optimized heart failure regimen in patients with New York Heart Association class III or IV symptoms of chronic heart failure due to systolic dysfunction. The Company has received "breakthrough designation" from the FDA for this MYDICAR program and expects to report results from this trial in April 2015.

29. On August 7, 2014, Celladon issued a press release announcing its second quarter 2014 financial results and recent highlights. The release stated in part:

"We have had very positive recent developments with MYDICAR. Last quarter's FDA Breakthrough Therapy designation validates MYDICAR's unique characteristics and clinical data to date and underscores the urgent need for new treatments for heart failure. Furthermore, the LVAD trial and plasma exchange initiative for AAV1 neutralizing antibody positive patients will potentially allow us to broaden the clinical utility of MYDICAR to a wider range of heart failure patients. In addition, we expect the MYDICAR arteriovenous fistula (AVF) maturation failure program and the Stem Cell Factor gene therapy programs to further increase the value of Celladon's emerging pipeline beyond our initial heart failure focus," said Krisztina Zsebo, Ph.D., Chief Executive Officer of Celladon.

* * *

MYDICAR®

- In April 2014 MYDICAR was granted Breakthrough Therapy designation by the Center for Biologics Evaluation and Research (CBER) division of the U.S. Food and Drug Administration (FDA) for reducing hospitalizations for heart failure in NYHA class III or IV chronic heart failure patients who are AAV1 neutralizing antibody negative, indicating that the FDA concluded that the CUPID 1 study data provided preliminary clinical evidence that MYDICAR may demonstrate substantial improvement over available therapies for advanced heart failure in these patients.
- In an effort to expand the population of heart failure patients with systolic dysfunction who may be eligible for MYDICAR treatment, in July 2014 we announced plans to conduct a pilot, 24 patient, Phase 1/2 clinical trial of MYDICAR in advanced heart failure patients with systolic dysfunction who have been previously excluded from MYDICAR studies in this indication due to pre-existing levels of neutralizing antibodies against the AAV1 vector. This study will examine whether a plasma exchange procedure can remove AAV1 neutralizing antibodies from the circulation prior to MYDICAR administration and therefore enable these patients to potentially be eligible for MYDICAR treatment. We expect to initiate this study in late 2014, and initial results are expected in 2015.
- In July 2014 we announced plans to conduct a 100 patient Phase 2a clinical trial with MYDICAR in end-stage renal disease (ESRD) patients undergoing surgery to create an AVF for hemodialysis. AVF maturation failure is a common problem in approximately half of the patients who undergo the procedure. Pending completion of additional preclinical work and approval by the FDA, the trial will evaluate MYDICAR's effect on improving blood flow in treated vessels and functional use of the fistula for hemodialysis. There are currently no FDA approved products to enhance AVF maturation. Initial results from this clinical trial are expected in 2015.

1 30. On August 11, 2014
2 first patient had been dosed in a
3 Feasibility of AAV1/SERCA2a
4 Left Ventricular Assist Device (
5 "The initiation of the to positively impact a will Krisztina Zsebo, Ph.D., LVAD patient population device treatment options valuable, and much need advanced heart failure pa
9 31. On September 26,

30. On August 11, 2014, Celladon issued a press release announcing that the first patient had been dosed in a clinical trial titled "Investigation of the Safety and Feasibility of AAV1/SERCA2a Gene Transfer in Patients with Heart Failure and a Left Ventricular Assist Device (LVAD)." The release stated in part:

"The initiation of this trial highlights the potential for MYDICAR to positively impact a wide range of cardiovascular conditions," said Krisztina Zsebo, Ph.D., Chief Executive Officer of Celladon. "The LVAD patient population has exhausted existing pharmaceutical and device treatment options. We believe MYDICAR may serve as a valuable, and much needed, new treatment modality for these very advanced heart failure patients."

31. On September 26, 2014, LifeSci Capital initiated coverage of Celladon with a report that stated in part:

Results from the CUPID 1 clinical trial indicate that high-dose MYDICAR delivered by intracoronary infusion may improve patient symptoms as well as reduce clinical events and time to hospitalizations. If this effect is confirmed in CUPID 2, then the cost-savings for hospitals and payers could make this therapy a very attractive option. This would increase both market penetration and eligible patient population as MYDICAR could be considered in less advanced disease as a means of slowing the progression of heart failure.

* * *

Heart Failure Represents a Significant Market Opportunity. According to the American Heart Association, there are about 6 million people in the United States and over 23 million people worldwide who suffer from heart failure (HF). We estimate that the target market for MYDICAR as currently indicated is around 360,000 patients in the US, with another 900,000 in Europe. HF is a severely debilitating condition, whereby the pumping of the heart cannot keep up with demands of the body that comes to affect all aspects of a patient's life.

Present therapies only aim to slow the progression of the disease, particularly during the early stages. This leaves an enormous opportunity for any therapy that can significantly reverse the disease course and reduce the number of cardiac events. If data from pivotal Phase III clinical trials supports approval, MYDICAR is positioned to potentially become the first disease-modifying therapy for advanced HF to enter the market. Such a treatment would not only greatly improve patients' lives, it has the potential to dramatically reduce costs associated with HF. The resulting pharmacoeconomic benefits would also further drive adoption of the product. Successful development of an efficacious disease-modifying treatment for advanced HF would likely be in high demand and drive significant value for Celladon.

| | 1 |
|---|---|
| | 2 |
| | 3 |
| | 4 |
| | 5 |
| | 6 |
| | 7 |
| | 8 |
| | 9 |
| 1 | 0 |
| | 1 |
| | 2 |
| 1 | 3 |
| 1 | 4 |
| 1 | 5 |
| 1 | 6 |
| 1 | 7 |
| 1 | 8 |
| 1 | 9 |
| 2 | 0 |
| 2 | 1 |
| 2 | 2 |
| 2 | 3 |
| 2 | 4 |
| 2 | 5 |
| 2 | 6 |
| 2 | 7 |
| 2 | 8 |

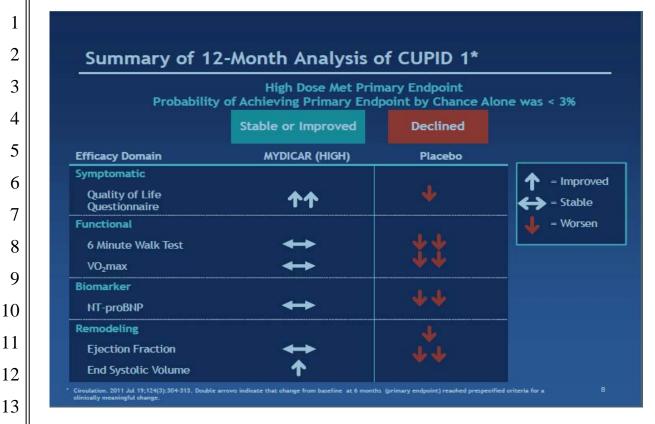
32. On November 12, 2014, Celladon issued a press release announcing its third quarter 2014 financial results and recent highlights. The release stated in pertinent part:

"Celladon had another productive quarter, in which we bolstered our balance sheet and observed progress across our product development portfolio. Importantly, the CUPID2 trial is proceeding according to plan, and we remain confident that we will be able to announce data from this trial in April 2015. CUPID2 is evaluating the use of MYDICAR to treat systolic heart failure, and we received Breakthrough Therapy designation for this program from the FDA in April of this year," said Krisztina Zsebo, Ph.D., Chief Executive Officer of Celladon.

Third Quarter 2014 and Recent Corporate Highlights

MYDICAR®

- In November 2014, we announced the execution of a facility construction and commercial supply agreement with Lonza Biologics, Inc. (Lonza). Under the agreement, Lonza will complete a detailed engineering design for the potential construction of a new commercial viral therapeutics facility in Portsmouth, New Hampshire for the manufacture of MYDICAR drug substance (AAV1/SERCA2a). In exchange for a reservation fee, we have the option, exercisable during a specified timeframe and with further financial obligation, to have Lonza commence construction of the facility and commit the parties to a multi-year agreement for commercial supply of MYDICAR.
- Also in the quarter, we had our fourth CUPID2 data safety monitoring committee (DMC) meeting where the DMC recommended we proceed with the trial as planned.
- 33. On November 17, 2014, CEO Zsebo presented at the American Heart Association's The Best of Circulation Research Symposium in San Diego. During the presentation, there was a slide showing the favorable results of CUPID1:



In summary, the presentation noted:

14

28

15 SUMMARY: CUPID 1 16 17 18 Clinical event rates are significantly lower three years following gene transfer in the high dose group compared to the placebo group 19 There were no untoward effects following MYDICAR delivery during the 3-year follow up 20 We found that MYDICAR results in persistence of SERCA2a gene up 21 to 31 months in cardiac tissues from patients injected with the high dose 22 In summary, the high dose met the pre-specified primary endpoint at 6 months, reduced HF hospitalizations at 1 and 3 years, trended 23 in improved survival, and demonstrated persistence of the transgene at late time points 24 25 26 27

34. On December 1, 2014, Celladon issued a press release announcing that Celladon's Executive Director of Biostatistics, Janice Pogoda, would present at the 11th Global Cardio Vascular Clinical Trail Forum on December 6, 2014. The release stated in part:

"We are honored that Janice has been selected to speak at the prestigious CVCT forum and believe it is a testament to our leadership in cardiovascular disease," said Krisztina Zsebo, Chief Executive Officer of Celladon. "Ongoing research and development is critical to ensure we are bringing the best therapies possible to patients and we are proud to support the efforts of CVCT."

- 35. Within a few weeks of the November 17, 2014 presentation and the Clinical Trial Forum, Celladon's stock increased from \$11.64 per share to \$18.05 per share.
- 36. On March 16, 2015, Celladon issued a press release entitled "Celladon Corporation Reports Inducement Grants Under NASDAQ Listing Rule 5635(c)(4)," which stated in part:

Celladon Corporation, a clinical-stage biotechnology company with industry-leading expertise in the development of cardiovascular gene therapy, today announced that on March 9, 2015 the Compensation Committee of the Company's Board of Directors approved the grant of inducement stock options to purchase a total of 40,000 shares of common stock to three new employees, with two of such grants having a grant date of March 9, 2015 (the "March 9 Grants") and the third having a grant date of March 11, 2015 (the "March 11 Grant"), with each such grant date corresponding to the employees' respective hire dates.

Each of the March 9 Grants has an exercise price per share equal to \$24.89, the fair market value on the grant date of the March 9 Grants. The March 11 Grant has an exercise price per share equal to \$25.99, the fair market value on the grant date of the March 11 Grant. Each stock option vests over the course of four years, with 25% vesting on the one-year anniversary of the employee's first day of employment with the Company and 1/48 of the shares vesting monthly thereafter, subject to the new employee's continued service relationship with the Company on each such date. Each stock option has a ten year term and is subject to the terms and conditions of the Company's 2013 Equity Incentive Plan and applicable stock option agreement.

Each of the stock options was granted as an inducement material to the new employees entering into employment with Celladon Corporation in accordance with NASDAQ listing Rule 5635(c)(4).

- 13 -

37. On March 19, 2015, the price of Celladon stock had increased to \$27.26 per share, its Class Period high.

38. On March 30, 2015, Celladon issued a press release announcing its fourth quarter and year-end 2014 financial results and recent highlights. The release stated in part:

"In the last year, Celladon has made significant progress in our clinical programs and pre-commercial planning for MYDICAR, including preparations for commercial manufacturing and other long lead-time activities. Our CUPID2 trial is evaluating the use of MYDICAR to treat systolic heart failure, known as HFrEF, and we received Breakthrough Therapy designation for this program from the FDA in April of last year. The CUPID2 trial is proceeding according to plan and we look forward to un-blinding and announcing top-line data from this trial in late April 2015. Following last year's financing activities, we are well positioned to advance our pipeline and development initiatives in 2015," said Krisztina Zsebo, Ph.D., Chief Executive Officer of Celladon.

Fourth Quarter 2014 and Recent Corporate Highlights

MYDICAR®

- In February 2015, we reached the last subject's last visit during the 12 month primary data analysis period in the CUPID2 study, thereby reaching the study's primary analysis data cutoff. We remain on track to un-blind the data and announce top-line results from this study in late April 2015.
- In December 2014, we commenced work with Novasep, Inc. (Novasep) for the potential future commercial manufacture of MYDICAR drug substance (AAV1/SERCA2a), and in March 2015, we announced the execution of a development, manufacturing and supply agreement with Novasep, which, if supported by the CUPID2 data, positions the parties to continue with the process transfer, facility retrofitting, development and manufacturing activities necessary for the future commercial supply of MYDICAR drug substance. If we proceed with the ongoing activities beyond a specified termination period following the un-blinding of CUPID2, we would commit to a multi-year agreement for the future commercial supply of MYDICAR drug substance.
- In November 2014, we announced the execution of a facility construction and commercial supply agreement with Lonza Biologics, Inc. (Lonza). In exchange for a reservation fee, we have the option, exercisable during a specified timeframe and with further financial obligation, to have Lonza commence construction of a new commercial viral therapeutics manufacturing facility, the exercise of which would commit us

to a multi-year agreement for the future commercial supply of MYDICAR drug substance.

- In December 2014, we conducted initial scale up of our MYDICAR (AAV1/SERCA2a) viral manufacturing process to 2,000 liter commercial scale, completing the first demonstration batch at Lonza's Houston facility.
- 39. On April 26, 2015, Celladon issued a press release, entitled "Celladon Reports Negative Results for CUPID2 Trial of MYDICAR^(R) in Advanced Heart Failure Investigational gene therapy fails to meet primary and secondary endpoints," which stated in pertinent part:

Celladon Corporation today announced that its Phase 2b CUPID2 trial did not meet its primary and secondary endpoints. CUPID2 is a randomized, double-blind, placebo-controlled, multinational trial evaluating a single, one-time, intracoronary infusion of the cardiovascular gene therapy agent MYDICAR® (AAV1/SERCA2a) versus placebo added to a maximal, optimized heart failure drug and device regimen.

In the study, the primary endpoint comparison of MYDICAR to placebo resulted in a hazard ratio of 0.93 (0.53, 1.65 95%CI) (p=0.81), defined as heart failure-related hospitalizations or ambulatory treatment for worsening heart failure. The secondary endpoint comparison of MYDICAR to placebo, defined as all-cause death, need for a mechanical circulatory support device, or heart transplant, likewise failed to show a significant treatment effect. The efficacy endpoint analyses were performed on the (n=243) modified intent to treat population (mITT), which excludes clinical events that occurred in patients who did not receive MYDICAR or placebo, or which occurred prior to dosing. All other exploratory efficacy endpoints (improvement in New York Heart Association classification, 6 Minute Walk Test, and Quality of Life) were also inconsistent with a treatment effect. No safety issues were noted.

"We are surprised and very disappointed that MYDICAR failed to meet the endpoints in the CUPID2 trial, and we are rigorously analyzing the data in an attempt to better understand the observed outcome. We would like to express our sincere gratitude to our investigators and patients who participated in the study," said Krisztina Zsebo, Ph.D., CEO of Celladon. "At the same time we are evaluating our other programs in order to determine the best path forward to maximize shareholder value."

"This trial was extremely well executed and adequately tested the hypothesis, but the therapy failed to achieve the primary and secondary endpoints. However, there were no safety issues," said Barry Greenberg, M.D., FACC, Director, Advanced Heart Failure Treatment Program; Distinguished Professor of Medicine, University of California, San Diego, and the Chairman of the Executive Clinical Steering Committee of the CUPID2 trial.

8

6

11

10

12

13 14

15 16

17

18

19

20 21

22

23

24

26

27

40. As a result of this news, the price of Celladon stock plummeted \$11.04 per share to close at \$2.64 per share on April 27, 2015, a decline of 80% on volume of 32 million shares.

41. On April 30, 2015, Celladon filed Form 8-K with the SEC, which stated in pertinent part:

Item 1.02 Termination of a Material Definitive Agreement.

Effective April 29, 2015, Celladon Corporation (the "Company") terminated the Development, Manufacturing and Supply Agreement by and between the Company and Novasep, Inc. ("Novasep") dated March 20, 2015 (the "Agreement") pursuant to the Company's post CUPID 2 data termination right, after concluding that the recently un-blinded data from the Company's Phase 2b clinical trial of MYDICAR (CUPID 2) was such that the Company does not require production of MYDICAR drug substance at Novasep's facility. The material terms of the Agreement are described in the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on March 25, 2015 filed with the Securities and Exchange Commission on March 25, 2015 and are incorporated herein by reference.

Item 2.05 Costs Associated with Exit or Disposal Activities.

As previously announced on April 26, 2015, the Company's CUPID 2 trial did not meet its primary and secondary endpoints. In light of these results, on April 26, 2015 the Company's Board of Directors approved an approximately 50% reduction of the Company's current full-time workforce of 34 employees in order to reduce operating expenses and conserve cash resources. The Company expects that a majority of employees included in this workforce reduction will be separated from the Company during the second quarter of 2015, with the remainder expected to be separated during the third quarter of 2015. The Company has also committed to retention payments payable to five key Company has also committed to retention payments payable to five key employees if such employees remain with the Company until December 31, 2015 or are terminated by the Company without cause prior to such date (the "Retention Plan"). The Company estimates that it will incur aggregate cash charges of approximately \$1.7 million associated with the workforce reduction and Retention Plan during 2015 in connection with approximately \$1.0 million in one-time severance payments, approximately \$0.1 million in continuation of benefits, approximately approximately \$0.1 million in continuation of benefits, approximately \$24,000 in outplacement service benefits and approximately \$0.6 million by December 31, 2015 in connection with retention payments.

42. In fact, defendants' statements about the prospects for the CUPID2 MYDICAR trial were materially false and misleading, as the CUPID1 trial was so small it was not indicative of any success and the low-dose and mid-dose levels in the CUPID1 trial had achieved results that were more comparable to the placebo, such that even the small CUPID1 trial had difficulty achieving results Celladon supposedly

5

8 9

10 11

13

12

14 15

16 17

18

19

20

22

21

23 24

25

26 27

28

expected from CUPID2. Due to the importance of MYDICAR to Celladon's business, the Company's top officers were keenly aware of the limitations of the results from the CUPID1 trial in predicting the success of the CUPID2 trial. Moreover, the Company was not well positioned financially for its 2015 initiatives.

- 43. On May 14, 2015, Celladon issued a press release announcing its first quarter 2015 financial results. The press release stated in pertinent part:
 - In April Celladon announced that its Phase 2b CUPID2 trial did not meet its primary or secondary endpoints. CUPID2 is a randomized, double-blind, placebo-controlled, multinational trial evaluating a single, one-time, intracoronary infusion of the cardiovascular gene therapy agent MYDICAR® (AAV1/SERCA2a) versus placebo added to a maximal, optimized heart failure drug and device regimen.
 - Also in April, Celladon terminated the Development, Manufacturing and Supply Agreement with Novasep, Inc. after concluding that the recently un-blinded CUPID2 data was such that Celladon does not require production of MYDICAR drug substance at Novasep's facility.
 - Similarly, Celladon does not intend to exercise the construction trigger option under the MYDICAR Facility Construction and Commercial Supply Agreement with Lonza Biologics, Inc., which will result in the automatic expiration of the agreement in the second quarter of 2015.
 - Celladon's Board of Directors approved an approximately 50% reduction of Celladon's current full-time workforce of 34 employees in order to reduce operating expenses and conserve cash resources.
 - Celladon will not be drawing down the second tranche of the debt facility with Hercules Technology Growth Capital, Inc. and will begin repaying the \$10 million principal currently outstanding in 30 equal monthly payments of principal and interest starting in August 2015.
- 44. On June 1, 2015, Celladon issued a press release announcing the abrupt resignation of defendant Zsebo as CEO and a director. The press release stated in part:

1
 2
 3

5

4

6 7

8

1011

12

13

1415

16

17

18

19

20

2122

23

24

2526

27

28

Celladon Corporation, today announced that its Board of Directors has unanimously approved a strategic plan pursuant to which the Company will immediately commence a process to seek an acquisition or partnership. The Company also announced that it has retained Wedbush PacGrow Healthcare as its exclusive financial advisor.

The Board also unanimously approved a leadership succession plan, pursuant to which Paul Cleveland has been promoted to Chief Executive Officer of Celladon and appointed to its Board of Directors, effective immediately. Krisztina Zsebo, Ph.D, who had been Celladon's Chief Executive Officer, has resigned from the Company and its Board of Directors. Following his vote in favor of these decisions, Patrick Y. Yang, Ph.D., also resigned from the Board of Directors. In addition, Andrew Jackson, previously the Company's Corporate Controller, was named Chief Financial Officer.

"We have unanimously determined that seeking an acquisition or partnership gives us the best opportunity to maximize shareholder value, and to that end we have retained Wedbush PacGrow Healthcare as exclusive financial advisor to the company and Board," said Michael Narachi, Chair of Celladon's Board of Directors. "In addition, with today's leadership announcement we enable a smooth transition to a proven executive in Paul Cleveland. We have the highest degree of confidence in Paul's leadership as we commence the process to seek an acquisition or partnership."

45. Then, on June 26, 2015, before the market opened, Celladon issued a press release entitled "Celladon Corporation Provides Business Update." The release stated in part:

Celladon Corporation today confirmed its plans to suspend further research or development of its MYDICAR (AAV1/SERCA2a) program and its other pre-clinical programs including the Stem Cell Factor (mSCF) gene therapy and SERCA2b small molecule programs.

Earlier in the month the Company announced the engagement of Wedbush PacGrow Healthcare as its exclusive financial advisor and a strategic plan pursuant to which the Company immediately commenced a process to seek a merger or sale. This process is ongoing and the Company expects to provide further updates on the progress of this strategic plan in the coming quarter, which could include the sale of the Company or some or all of its assets, and/or a liquidation and distribution of the remaining cash to its shareholders.

"Our Board of Directors has unanimously determined that seeking a merger or sale, in lieu of further development of our remaining programs and assets, gives us the best opportunity to maximize shareholder value. We are aggressively pursuing that course," said Paul Cleveland, president and chief executive officer of Celladon. "If we are unable to identify a merger or sale that provides superior value to our shareholders, we will move forward with a liquidation and distribution of net cash to shareholders."

The Company currently estimates that if it were to liquidate during the third quarter of 2015, the net cash available for distribution to shareholders would be approximately \$25-\$30 million. This projection is based on the Company's current expectations and assumptions, and the actual amount of net cash available for distribution in such a liquidation and distribution could differ materially from the Company's current estimate.

The Company also announced a second reduction in its workforce, with approximately half of the employees not previously notified of termination of employment being expected to depart in the third quarter. "Our employees have been performing with exceptional professionalism under difficult circumstances, and on behalf of the Board I would like to thank them for their efforts," said Mr. Cleveland.

- 46. As a result of this news, the price of Celladon stock dropped \$0.85 per share to close at \$1.35 per share on June 26, 2015, a decline of 38% on volume of 9 million shares.
- 47. As a result of defendants' false statements, Celladon securities traded at artificially inflated prices during the Class Period. However, after the above revelations seeped into the market, the Company's shares were hammered by massive sales, sending the Company's stock price down 95% from its Class Period high and causing economic harm and damages to Class members.

LOSS CAUSATION/ECONOMIC LOSS

48. During the Class Period, defendants made false and misleading statements by misrepresenting the materiality of the interim clinical data and engaged in a scheme to deceive the market. Defendants' conduct artificially inflated the prices of Celladon securities and operated as a fraud or deceit on the Class. Later, when defendants' prior misrepresentations were disclosed to market participants, the prices of Celladon securities plummeted, as the prior artificial inflation came out of the prices. As a result of their purchases of Celladon securities during the Class Period, plaintiff and members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

APPLICABILITY OF THE PRESUMPTION OF RELIANCE AND FRAUD ON THE MARKET

- 49. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:
- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
 - (b) The omissions and misrepresentations were material;
 - (c) The Company's stock traded in an efficient market;
- (d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- (e) Plaintiff and other members of the Class purchased Celladon securities between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.
- 50. At all relevant times, the market for Celladon securities was efficient for the following reasons, among others:
- (a) Celladon stock met the requirements for listing, and was listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, Celladon filed periodic public reports with the SEC; and
- (c) Celladon regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services.

2

3 4

5

7

8 9

10

11 12

13 14

15

16

17

18

19

20

21

22 23

24

26

27

28

NO SAFE HARBOR

- 51. Many (if not all) of defendants' false and misleading statements during the Class Period were not forward-looking statements ("FLS") and/or were not identified as such by defendants, and thus did not fall within any "Safe Harbor."
- 52. Celladon's verbal "Safe Harbor" warnings accompanying its oral FLS issued during the Class Period were ineffective to shield those statements from liability.
- 53. Defendants are also liable for any false or misleading FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false or misleading and the FLS was authorized and/or approved by an executive officer of Celladon who knew that the FLS was false. Further, none of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made.

CLASS ACTION ALLEGATIONS

- Plaintiff brings this action as a class action pursuant to Rule 23 of the 54. Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Celladon publicly traded securities during the Class Period (the "Class"). Excluded from the Class are defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which defendants have or had a controlling interest.
- 55. The members of the Class are so numerous that joinder of all members is impracticable. The Company's stock is actively traded on the NASDAQ and there are over 23.8 million shares of Celladon stock outstanding. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds of members in

--

the proposed Class. Record owners and other members of the Class may be identified from records maintained by Celladon or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

- 56. Common questions of law and fact predominate and include whether: (i) defendants violated the 1934 Act; (ii) defendants omitted and/or misrepresented material facts; (iii) defendants knew or recklessly disregarded that their statements were false; and (iv) defendants' statements and/or omissions artificially inflated the prices of Celladon securities and the extent and appropriate measure of damages.
- 57. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.
- 58. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.
- 59. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

COUNT I

For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants

- 60. Plaintiff incorporates ¶¶1-59 by reference.
- 61. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material

9 10

12

11

14

13

16

15

17 18

19

20

21

2223

24

2526

27

under which they were made, not misleading.

62. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

facts necessary in order to make the statements made, in light of the circumstances

- (a) Employed daying schemes and artifices to defroud
- (a) Employed devices, schemes, and artifices to defraud;
- (b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Celladon securities during the Class Period.
- 63. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Celladon securities. Plaintiff and the Class would not have purchased Celladon securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.
- 64. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of Celladon publicly traded securities during the Class Period.

COUNT II

For Violation of §20(a) of the 1934 Act Against All Defendants

- 65. Plaintiff incorporates ¶¶1-64 by reference.
- 66. During the Class Period, defendants acted as controlling persons of Celladon within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about Celladon, the Individual Defendants had the power and ability to control the actions of Celladon and its employees. Celladon controlled the Individual Defendants and its other officers and

| 1 | employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the | | | |
|-----|--|---|---|--|
| 2 | 1934 Act. | | | |
| 3 | PRAYER FOR RELIEF | | | |
| 4 | WHEREFORE, plaintiff prays for judgment as follows: | | | |
| 5 | A. | A. Determining that this action is a proper class action, designating plaintiff | | |
| 6 | as Lead Plaintiff and certify plaintiff as a class representative under Rule 23 of the | | | |
| 7 | Federal Rules of Civil Procedure and plaintiff's counsel as Lead Counsel; | | | |
| 8 | В. | B. Awarding plaintiff and the members of the Class damages and interest; | | |
| 9 | C. Awarding plaintiff's reasonable costs, including attorneys' fees; and | | | |
| 10 | D. | D. Awarding such equitable/injunctive or other relief as the Court may deem | | |
| 11 | just and proper. | | | |
| 12 | JURY DEMAND | | | |
| 13 | Plaintiff demands a trial by jury. | | | |
| 14 | DATED: J | July 2, 2015 | ROBBINS GELLER RUDMAN | |
| 15 | | | DAVID C. WALTON | |
| 16 | | | | |
| 17 | | | s/David C. Walton DAVID C. WALTON | |
| 18 | | | 655 West Broadway. Suite 1900 | |
| 19 | | | San Diego, CA 92101-8498 Telephone: 619/231-1058 619/231-7423 (fax) | |
| 20 | | | 619/231-7423 (fax) | |
| 21 | | | LAW OFFICES BERNARD M. | |
| 22 | | | GROSS, P.C. DEBORAH R. GROSS | |
| 23 | | | Wanamaker Bldg., Suite 450 | |
| 24 | | | 100 Penn Square East Philadelphia, PA 19107 | |
| 25 | | | Telephone: 215/561-3600 | |
| 26 | | | 215/561-3000 (fax) | |
| 27 | | | | |
| 28 | | | | |
| - 1 | I | | | |

KENNETH A. ELAN ATTORNEY AT LAW 217 Broadway, Suite 603 New York, New York 10007 Telephone: 212/619-0261 212/385-2707 (Fax) Attorneys for Plaintiff I:\Admin\CptDraft\Securities\Cpt Celladon.docx